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09/486,065	03/30/2000	MARC DOLATKHANI	BIF103705/US	3112

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/486,065**

Applicant(s)  
**Dolatkhani et al.**

Examiner  
**First Last**

Art Unit  
**1234**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov 12, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 19-65 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's request for reconsideration of the restricted claims 44-63 withdrawn in the last Office action is persuasive and, therefore, the claims have been examined on the merits.

### ***Claim Rejections - 35 U.S.C. § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The product resulting with covalent bonds which is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Although Applicant points out that certain polymers can join to have covalent bonds, there is no written support in the specification for this limitation .

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 35, 47, 59-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 recites the limitation "the monofunctional agent" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 47 recites the limitation "the chemical reaction of polymeric and copolymeric material" in line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 60 recites the limitation "the network" in line 6 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claims 59, 61 recite the limitation "the polyfunctional reactive compound" in lines 3 and 6 respectively of the claims. There is insufficient antecedent basis for this limitation in the claims.

#### *Claim Rejections - 35 U.S.C. § 102*

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes

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of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 19-21,23,24,27-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Vanderbilt (5326506). Vanderbilt discloses a soft optical part and a rigid haptic part, col. 3, lines 45-52 and col. 5, lines 39-42. The method of forming the device, i.e. "having a structural chemical modification" is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight. Regarding claims 21,23,24,33 see col. 5, lines 59-68 and col. 6, lines 52-54. With respect to claims 28-31, see col.7, lines 61-68 and col. 8, lines 1-12 suggesting that a "zone" can be established to join the two parts of rigid material and flexible material. Fig. 3 shows element 46 which can be construed as an attachment member.

7. Claims 19-23,26-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Bos et al. (5762836). See claims. Bos et al. disclose that the flexible material can be hydrophilic, col. 11, lines 24-29. Bos et al. also disclose that polymer materials, such as polydimethylsiloxanes are suitable for the intraocular lens, col. 12, lines 32-34. The method of forming the device, i.e. "having a structural chemical modification" is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight.

8. Claims 44-52,54,56-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Lohmann et al. (6271332). Lohmann et al. disclose a method of making an intraocular lens by structurally modifying a flexible material, col. 15, lines 45-56. Lohmann also discloses the

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modification of the material can be done after the shaping of the pre-form into a IOL, col. 14, lines 65-67, col. 15, lines 1,2. Lohmann additionally discloses modifying the material outside the material with monomers, col. 16, lines 30-36. Regarding claim 52, Lohmann does not disclose the step of shaping after the structural modification of the material. It would have been a matter of design of choice to perform the shaping after the structural modification, since applicant has not disclosed that the order of steps are followed in a particular order for any purpose or solve any stated problem, or provides any advantage. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to result in an equally effective product with either the method as taught by Lohmann or the claimed shaping following modification of the material because both methods produce the same shaped and structurally modified product .

Regarding claim 57, Lohmann does not disclose the modification of the material inside the material. It would have been a matter of design of choice to have the structural modification within the material, since applicant has not disclosed that the location of modification is for any purpose or solves any stated problem, or provides any advantage. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to result in an equally effective product with either the method as taught by Lohmann or the claimed structural modification within the material because both methods produce a flexible structurally modified product .

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9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 25,36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderbilt '506 in view of Freeman et al. (5693095). Vanderbilt is explained supra. Vanderbilt does disclose that crosslinking agents are added in the materials, col. 4, lines 12-15. However, Vanderbilt does not disclose the use of the polyfunctional agent diethylene glycol dimethacrylate. Freeman et al. teach the use of diethylene glycol dimethacrylate for crosslinking copolymers, col. 3, lines 3-15. It would have been obvious to one of ordinary skill in the art at the time of the invention to use an alternative crosslinking agent such as diethylene glycol dimethacrylate as taught by Freeman for crosslinking copolymer materials of Vanderbilt, in order to affect the rate of reaction.

11. Claims 34, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderbilt '506 in view of Sherr et al. (3391224). Vanderbilt is explained supra. Vanderbilt does disclose that crosslinking agents are added in the materials, col. 4, lines 12-15. However, Vanderbilt does not disclose the agent used in crosslinking as monofunctional. Sherr et al. teach that a monofunctional agent, i.e. styrene is used in a polymerization reaction to aid in forming a thermosetting composition. It would have been obvious to one of ordinary skill in the art at the time of the invention to use an monofunctional agent in crosslinking to increase the stability and formability of the intraocular lens.

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12. Claims 36-43,64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderbilt '506 in view of Wang et al. (6011082). Vanderbilt is explained supra. Vanderbilt does disclose that crosslinking agents are added in the materials, col. 4, lines 12-15. However, Vanderbilt does not disclose the agent used in crosslinking as polyfunctional. Wang et al. teach to use a coupling agent in the polymerization process of copolymers to provide a surface modification with long-term stability. Wang also teaches that the reaction is done with a polyfunctional agent, col. 5, lines 1-7. It would have been obvious to one of ordinary skill in the art to use a polyfunctional agent in the modification of the material to stabilize it. As a result this will enhance the longevity of the prosthesis.

Claims 53,55,62,63,65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohmann et al. '332 in view of Vanderbilt '506. Lohmann is explained supra. Lohmann additionally discloses functional agents such as isocyanate, col. 18, lines 3-5 and also carboxylic compounds, col. 17, lines 53-55. However, Lohmann et al. do not disclose using a random (MMA-HMA) copolymer. Vanderbilt teaches the use of MMA in a IOL, col. 8, lines 5-9 and also that PMMA is used in the lens material, col. 7, lines 65-66. It would have been obvious to one of ordinary skill in the art to use MMA-HMA as taught by Vanderbilt in the method of Lohmann et al. in order to provide a material having strong bonds.



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*Response to Arguments*

13. Applicant's arguments filed 11/12/02 have been fully considered but they are not persuasive. A comparison of the recited process with the prior art processes for the rejection of the product claim, does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S.P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3.

*Conclusion*

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino

December 2, 2002

  
Paul Prebilit  
Primary Examiner  
TC 3700, AU 3738